

Application No. 09/815,573
Amendment Dated April 20, 2006
Reply to Office Action of January 20, 2006

REMARKS

In the Office Action dated January 20, 2006, claims 8-14 were examined with the result that all claims were rejected. In response, Applicant submits the following comments. In view of these remarks, reconsideration of this Application is requested.

In the Office Action, claims 8-14 were rejected under 35 USC §103(a) as being unpatentable over DeLuca et al WO 96/24258 in view of Smith et al U.S. 5,145,695. The Examiner states that the '258 reference describes a method of improving utilization of phytate phosphorus so as to reduce or minimize or perhaps eliminate dietary requirements of phosphorus in commercially significant animals, such as cattle. Smith et al teaches that dairy cows are commercially significant animals and thus the Examiner concludes that one skilled in the art would have been motivated to replace all inorganic phosphorus in a dairy cows diet in view of the disclosure in the '258 reference. The Examiner states that the '258 reference provides the motivation for the present method of eliminating dietary requirements of phosphorus while maintaining milk production in dairy cows. Applicant, however, respectfully disagrees for the following reasons.

Assuming the Examiner has made a prima facie case of obviousness, Applicant may rebut that prima facie case with evidence. As stated in In re Kumar et al, 76 USPQ 2d 1048 (2005), the Court of Appeals for the Federal Circuit stated:

"An applicant may rebut a prima facie case of obviousness by providing a 'showing of facts supporting the opposite conclusion.' Such a showing dissipates the prima facie holding and requires the examiner to 'consider all of the evidence anew.' Piasecki, 745 F.2d at 1472; In re Rinehart, 531 F.2d 1048, 1052 (CCPA 1976). Rebuttal evidence may show, for example, that the claimed invention achieved unexpected results relative to the prior art, In re Geisler, 116 F.3d 1465, 1469-70 (Fed. Cir. 1997); that the prior art teaches away from the claimed invention, *id.* at 1471; that objective evidence (e.g., commercial success) supports the conclusion that the invention would not have been obvious to a skilled artisan, Piasecki, 745 F.2d at 1475; or that the prior art did not enable one skilled in the art to produce the now-claimed invention. In re Payne, 606 F.2d 303, 314-15 (CCPA 1979)."

As noted above, one of the ways that Applicant can rebut a prima facie case of obviousness is to show that the prior art teaches away from the claimed invention. To show this, Applicant has enclosed three published documents relating to the phosphorus requirements for dairy cows. These articles are:

1. "Feeding Dairy Cows," a publication of Kansas State University dated January, 1989.
2. Harris et al, "Phosphorus Nutrition and Excretion by Dairy Animals," published by the University of Florida, June, 2003.
3. Grant et al, "Lesson 12: Feeding Dairy Cows to Reduce Nutrient Excretion," published by Midwest Plan Service, 2006.

Each of the above articles spanning approximately 17 years and associated with Kansas State University, University of Florida and the 12 land grant universities listed by Midwest Plan Service such as the University of Illinois, Iowa State University, Michigan State University, etc., all state that phosphorus is not adequately supplied by most feedstuffs and as a result, phosphorus must be supplemented in some manner. Applicant has highlighted some specific areas in each of the above three articles for the convenience of the Examiner. In each case, however, the Examiner will note a continuous supply of supplemental phosphorus must be provided to dairy cows in order to maintain high levels of milk production. The Examiner will note that in each of the articles the authors do not say "might be required" or "possibly need to be supplied," but in every case the authors of these articles state the phosphorus supplementation is "required." Thus, to those skilled in the art, one would not believe it "reasonable" to eliminate all supplemental inorganic phosphorus from the diet of a milk producing dairy cow. All of these references, and Applicant could cite additional published articles in addition to the three noted above, "teach away" from Applicant's claimed invention herein. It is simply not reasonable for one skilled in the art to believe that one could eliminate all supplemental inorganic

phosphorus from the diet of a dairy cow and still maintain adequate high milk production. Obviously, the production of milk in dairy cows causes a large phosphorus drain on the cow's system. Applicant has unexpectedly discovered that one can maintain milk production without added inorganic phosphorus by also feeding 1α -hydroxylated vitamin D compounds. The prior art, on the other hand, teaches away from Applicant's invention, and instead states that inorganic phosphorus must be added to the cow's diet.

Another way cited in the In re Kumar, et al, supra, case that Applicant may rebut a prima facie case of obviousness is to show that the prior art did not enable one skilled in the art to produce the now claimed invention. Although published subject matter is "prior art" for all that it discloses, in order render an invention unpatentable for obviousness, the prior art must enable a person of ordinary skill in the art to make and use the invention. Thus, when a prima facie case of obviousness is made, rebuttal may take the form of evidence that the prior art does not enable the claimed subject matter. Clearly, the prior art cited by the Examiner does not enable the now claimed invention. There is nothing in the '258 reference or the '695 reference which teaches one skilled in the art that milk production in dairy cows may be maintained despite the fact that all inorganic phosphorus in the diet of the dairy cow has been removed and replaced with an effective amount of a 1α -hydroxylated vitamin D compound. Clearly, there is nothing in Smith et al '695 which would teach this, and with regard to the '258 reference, it is directed solely to the increased utilization of phytate phosphorus, i.e. organic phosphorus, and does not provide any data to support the claim to eliminating inorganic phosphorus from the diet of dairy cows while maintaining milk production. Although the abstract of the '258 reference does refer to reduction of supplemental inorganic phosphorus due to the use of vitamin D compounds, it does so only in the context that vitamin D compounds increase utilization of phosphorus from the phytate complex.

The use of the word "perhaps" when referring to eliminating the need for supplemental quantities of phosphorus in an animal's diet is significant. The word "perhaps" is defined as "a possibility but not a certainty." Such definition is clearly not an

affirmative teaching, much less an enabling disclosure, to one skilled in the art that one can eliminate all phosphorus in a dairy cow's diet and at the same time maintain milk production in the dairy cow. The word "perhaps" implies that further work needs to be performed in order to determine whether something is a certainty. This falls far short of an enabling disclosure to one skilled in the art that all supplemental inorganic phosphorus can be replaced in a dairy cow's diet and still maintain adequate milk yield. Thus, Applicant believes that the prior art combination cited by the Examiner does not enable one skilled in the art to perform the now claimed invention.

Finally, Applicant notes that an invention is not obvious where the prior art only provides an "invitation to explore" even though the prior art could theoretically explain the invention. This is the holding in the case of Ex parte Obukowicz, 27 USPQ 2d 1063 (B.P.A.I. 1992). In Ex parte Obukowicz, the invention concerned a method of combating plant insect pests using plant colonizing bacteria that had been genetically modified to produce a specific protein toxin. The modification was accomplished by inserting DNA encoding for the protein toxin into the chromosome of the bacteria. The genetically modified bacteria were applied to the plant or plant seed environment, which expressed the insecticidally active protein toxin consumed by plant pests.

The claimed invention was rejected as obvious in view of the reference Dean combined with various secondary references. The principal issue was whether, based on Dean, the suggestion or motivation was provided to render the claimed invention obvious (i.e., the incorporation of the gene into the chromosome of bacteria that produced the protein in the plant environment).

The Board held that a statement in Dean regarding combating mosquitoes using genetically engineered "natural pond microflora" was insufficient to provide the necessary suggestion or modification. As stated by the Board:

"[T]he specific statement by Dean is not a suggestion to insert the gene into the chromosome of bacteria and apply that bacteria to the plant environment in order to protect the plant. At best, the Dean statement is but

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an invitation to scientists to explore a new technology that seems a promising field of experimentation. The Dean statement is of the type that gives only general guidance and is not at all specific as to the particular form of the claimed invention and how to achieve it. Such a suggestion may make an approach "obvious to try" but it does not make the invention obvious."

The Board even added the following statement:

"We recognize that given the teachings in appellant's specification regarding incorporation of the gene into the chromosome and utilizing the bacteria in the plant environment, one can theoretically explain the technological rationale for the claimed invention using selected teachings from the references. This approach, however, has been criticized by our reviewing court as hindsight reconstruction."

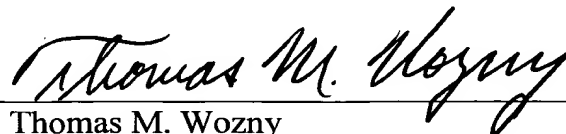
Like the holding in Obukowicz, the most that can be said about the phrase in the abstract of the '258 reference referring to "perhaps" eliminating the need for supplemental quantities of phosphorus in an animal diet is that it presents an "obvious to try" approach to the invention, but as noted above, such an approach does not make the present claimed invention obvious. The phrase "perhaps eliminating" appears to provide an invitation to explore a new technology to one skilled in the art, but that does not make the present invention obvious.

An effort has been made to place this application in condition for allowance and such action is earnestly requested.

Respectfully submitted,

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